



Better health through laboratory medicine

March 20, 2014

The Honorable Mary L. Landrieu  
Hart Senate Office Building, SH-703  
Washington, DC 20510-1804

Dear Senator Landrieu:

The American Association for Clinical Chemistry is requesting your assistance to ensure that patients receive safe, quality health care. A key element of nearly all patient interactions within the health care system is laboratory tests. These tests are highly accurate and play a key role in assessing patient health. One aspect of laboratory testing that needs to be addressed is the 'harmonization' of laboratory test results (i.e., when a patient's sample, measured by different laboratory methods, gives the same result).

In today's evidenced-based environment, clinical practice guidelines are used to help physicians make informed patient care decisions. These guidelines frequently rely upon laboratory test results to establish a cutoff point for determining if and when clinical intervention is necessary (e.g, above the cutoff take action, below don't). We are concerned that clinicians may not understand that different laboratory methods may give different numeric values for the same test. Although each result may be accurate, applying clinical practice guidance in the absence of harmonized test results could contribute to clinician error and harm to the patient.

AACC believes that test results should be comparable irrespective of the laboratory, method or time when measurements are made. Comparable (harmonized) test results would permit clinicians to better monitor and interpret a patient's condition over time, improve the quality of clinical practice guidelines, enhance the clinical research data used in developing guidelines, and make test results a more meaningful component of electronic health records. A lack of recognition that results may be neither standardized nor harmonized may hinder efforts to improve the quality of health care.

The ideal practice for ensuring that laboratory results are in agreement is to calibrate each device or method to a known standard reference method or to a certified reference material. Currently, these standard reference methods and certified reference materials are only available for a small portion of the more commonly ordered laboratory tests. The best alternative is to 'harmonize' the test outcomes by way of correlation studies, thereby generating a common numeric value for the health care professional and patient. AACC is working with other laboratory medicine professional societies around the world to advance this approach and improve overall patient care. We are requesting your assistance to help us accomplish this objective.

Senator Landrieu

March 20, 2014

Page Two

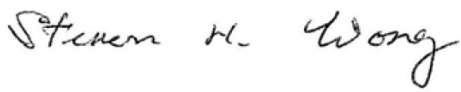

AACC, with the help of medical device manufacturers, physicians, professional laboratory scientists and standards development organizations, among others, created an International Consortium for Harmonization of Clinical Laboratory Results to develop a global approach for prioritizing, organizing and managing the harmonization of clinical laboratory test results. This is a long-term initiative to develop comparable test results to improve the quality of patient care, while also reducing unnecessary costs. AACC would like your help in raising awareness of this issue among policymakers and promoting the need for public-private collaboration in this area.

We are requesting that you include report language (see the attached language) in a forthcoming health-related bill, such as HHS Appropriations, that recognizes this problem and encourages federal health agencies to work with the private sector to address this ongoing issue. Although we are currently working with officials within a number of federal agencies, this is a problem that needs greater recognition within HHS to ensure that we can develop and sustain the public-private network needed to harmonize test results.

AACC has also developed a position statement that more fully examines harmonization and its importance to improving health care. In addition, the document identifies other key stakeholders and their roles in advancing this initiative. I am enclosing a copy of this statement. AACC looks forward to working with you on this important issue.

By way of background, AACC is the principal association of professional laboratorians--including MDs, PhDs and medical technologists. AACC's members develop and use chemical concepts, procedures, techniques and instrumentation in health-related investigations and practice in hospitals, independent laboratories and the diagnostics industry worldwide. The AACC provides international leadership in advancing the practice and profession of clinical laboratory science and medicine and its applications to health care. If you have any questions, please call me at (336) 716-2639, or Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Sincerely,

Steven H. Wong, Ph.D., DABCC (TC), FACB  
President, AACC

**Harmonization of Laboratory Test Results** –Laboratory professionals use a variety of test methods to obtain accurate and informative results to diagnose and treat patients. The use of different laboratory test methods may result in the reporting of different numeric values for the same test. Developing a process to ‘harmonize’ these differing laboratory numbers into a common value is critical to reducing medical errors, improving the quality of care and empowering patients to participate in decisions affecting their care. In addition, comparable patient laboratory results will provide added value to patient electronic health records, enabling more effective information sharing. The Committee urges the Department of Health and Human Services to partner with the private sector in ‘harmonizing’ clinical laboratory test results. Further, the Centers for Disease Control and Prevention, given its extensive experience in this area, should be an active participant in any public-private harmonization initiative